Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claim 37, under 35 U.S.C. §112, second paragraph. Applicants respectfully traverse the rejection.

The Examiner states that the claim is indefinite based on the use of the word "derived" and indicates that the Office assumes it means any amino acid (Office Action, at page 2). Applicants respectfully submit that a peptide is understood to include more than one amino acid because it must have a peptide bond between at least two amino acids. Thus, the Examiner's interpretation of the claim as meaning "any amino acid" is erroneous. Applicants assert that the meaning of the word "derived" in the phrase "peptides derived from the amino acid sequence of said at least one protein" as used in claim 37 is a term of art that would be understood by one of ordinary skill to mean a peptide with an amino acid sequence that comes from, i.e., is a fragment of, the amino acid sequence of a protein that is encoded by a nucleic acid molecule comprising a nucleotide sequence set forth in SEQ ID NO:1, 2, 3, 4, or 5. To further clarify the metes and bounds of the claim, Applicants have amended claim 37 to indicate that the derived peptide is an immunogenic derived peptide that binds to an MHC molecule. Applicants submit that one of ordinary skill in the art would recognize a peptide of amended claim 37 as an immunogenic peptide that includes part of the amino acid sequence of a protein of the invention that is encoded by SEQ ID NO:1, 2, 3, 4, or 5, and not "any amino acid". Moreover, by virtue of the requirement of MHC binding, one of ordinary skill in the art would recognize that the peptide must be of sufficient length to bind MHC. (Typically nine or ten amino acids for MHC class I binding). Applicants submit that the amended claim 37 is clear as to the metes and bounds of claim 37 and thus obviates the rejection.

Applicants respectfully request the Examiner reconsider and withdraw the rejection of claim 37 under 35 U.S.C. §112, second paragraph.

Rejection under 35 U.S.C. §112, First Paragraph

The Examiner reinstated the previous rejection of claim 6 under 35 U.S.C. §112, first paragraph as lacking an adequate written description. Applicants respectfully traverse the rejection.

Applicants have provided the nucleotide sequence of each of the nucleic acid molecules set forth as SEQ ID NOs:1-5, and teach uses for the molecules as well as how to use them to practice the invention. Applicants have amended claim 6 to indicate that the nucleic acid

molecules encode a cancer antigen that stimulates an immune response. Applicants submit that amended claim 6 provides a description of activity of claimed proteins as required by the Examiner. Applicants have also amended claim 6 to include the high stringency hybridization conditions under which sequences highly related to sequences that encode the claimed proteins would hybridize. Applicants respectfully submit that the inclusion of the high stringency conditions in the claim obviates the issue concerning unpredictability of members of the claimed genus. Applicants assert that given the sequences provided, (SEQ ID NO:1-5), the high stringency conditions for hybridization to those sequences, and inclusion of the stimulation of an immune response as an activity of claimed proteins, one of ordinary skill in the art would recognize that Applicants indeed had possession of the claimed invention at the time of filing.

On the basis of the amendments and arguments presented herein, Applicants respectfully request the Examiner reconsider and withdraw the rejection made under 35 U.S.C. 112, first paragraph.

Rejection under 35 U.S.C. §102(e)

The Examiner rejected claim 37-40 under 35 U.S.C. 102(e) as anticipated by U.S. Patent No.: 5,840,839 (the '839 patent). Applicants respectfully traverse the rejection.

The Examiner based the rejection on the interpretation of the "derived" language in claim 37 as meaning any amino acid (Office Action at page 3). The Examiner also interprets claim 37-40 as being drawn to "any antigenic cancer peptide" (Office Action, at page 4). As described above, Applicants submit that the Examiner's interpretation of the word "derived" in claim 37 is erroneous. The claim is drawn to a composition of matter that stimulates an immune response to at least one protein encoded by at least one nucleic acid molecule comprising a nucleotide sequence set forth in SEQ ID NO: 1, 2, 3, 4, or 5. The claimed composition comprises a plurality of immunogenic peptides that are derived from, e.g. are fragments of, the amino acid sequence of one or more of the proteins. Thus, the immunogenic peptides clearly do not encompass "any antigenic cancer peptide" as suggested by the Examiner, but rather encompasses antigenic peptides with amino acid sequences that are included in the amino acid sequences of the proteins encoded by SEQ ID NO:1-5.

The '839 patent relates to the normal melanogenic gene, gp75 gene, which encodes a gene product, a 24 amino acid peptide of ORF3 (see '839 Abstract). The sequence of the gp75 gene is different than any of SEQ ID NOs:1-5. Applicants respectfully assert that the antigenic peptides

of the instant invention are not encoded by the gp75 gene and thus are not described or taught in the '839 patent. Because the '839 patent does not teach the elements of the claimed invention, Applicants submit that the reference does not anticipate the invention as claimed. Applicants therefore request the rejection of claims 37-40 under 35 U.S.C. §102(e) be withdrawn.

In view of the foregoing, Applicants respectfully request that the Examiner withdraw the rejections and act favorably upon the claims.

Respectfully submitted,

MaryDilys S. Anderson
Reg. No. 52,560
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, MA 02210
Tel. (617)720-3500

Attorney Docket No. L00461.70081.US
Date: May 4, 2003
X06/13/03

Marked-up Claims

6. (Thrice Amended) An isolated protein encoded by an isolated nucleic acid molecule selected from the group consisting of:

(a) nucleic acid molecules which encode a cancer [associated] antigen that stimulates an immune response, and which comprise a nucleotide sequence, the complementary sequence of which hybridizes, under stringent conditions, to at least one second nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of the nucleotide sequences set forth as SEQ ID NOs: 1, 2, 3, 4, and 5,

(b) nucleic acid molecules that differ from the nucleic acid molecules of (a) in codon sequence due to the degeneracy of the genetic code, and

(c) full length complements of (a) or (b), wherein the stringent conditions are hybridization at 65°C in hybridization buffer (3.5x SSC, 1x Denhardt's solution; 25 mM sodium phosphate buffer (pH 7.0), 0.5% SDS, 2mM EDTA), wherein SSC is 0.15M sodium chloride/0.015M sodium citrate, pH7; wherein SDS is sodium dodecyl sulphate, and EDTA is ethylenediaminetetraacetic acid.

37. (Twice Amended) A composition of matter useful in stimulating an immune response to at least one protein encoded by at least one nucleic acid molecule comprising a nucleotide sequence set forth in SEQ ID NO: 1, 2, 3, 4 or 5, said composition comprising a plurality of immunogenic peptides derived from the amino acid sequence of at least one of the said proteins [at least one protein], wherein said peptides bind to one or more MHC molecules presented on the surface of cells [which express an abnormal amount of said at least one protein].